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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/462,480	03/06/00	GICQUEL	9660-0165-0X

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 07/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/462,480	Gicquel et al
Examiner	**Art Unit**
Rodney P. Swartz, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *27December2000*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above, claim(s) *1-15, 25, 30, 32, and 34-55* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16-24, 26-29, 31, and 33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-55* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicants' Response to Restriction, received 27December2000, paper#11, is acknowledged. Applicants elect, with traverse, Group II, claims 16-24, 26-29, 31, 33, drawn to polypeptides and methods of diagnosis.

The traversal is on the grounds that the examiner has not explained why each group lacks unity with each other group and has not specifically described the unique special technical features in each group to justify the conclusion of a lack of unity of invention nor shown that a search of all the claims would impose a serious burden on the Office. . This is not found persuasive because each Group is drawn to a separate special technical feature, Group I to DNA, Group II to polypeptides, Group III to antibodies. Each special technical feature is functionally and structurally distinct from each other and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper...

The requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 1-15, 25, 30, 32, and 34-55 are withdrawn from further consideration pursuant to 37 CAR 1.142(b), as being drawn to a nonelected invention.

2. Claims 16-24, 26-29, 31, and 33 are currently under consideration.

Drawings

3. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Specification

4. This application lacks the necessary reference to the application to which is claims priority. A statement reading "This is a ------ of -------- , filed ." should be entered as the first sentence of the specification.

5. The disclosure is objected to because of the following informality:

a) page 54, line 27, "attibuable" should be "attributable",

b) page 55, line 19, "M. tub" should be "*M. tuberculosis*", lines 21 and 28, "were" should be "where", lines 24 and 29, "Cattles" should be "Cattle"

c) page 34, lines 7 and 8, it is unclear what is meant by "aminoacyles".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16-24, 26-29, 31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent from a nonelected claim 9.

9. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to "portions of the polypeptide of SEQ ID NO 4". However, SEQ ID NO:4 is a nucleic acid sequence.

10. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, because the claims recite the limitation "portions of polypeptide of SEQ ID NO4" according to claim 18. There is insufficient antecedent basis for this limitation in the claims as neither claim 18 nor claim 17 nor 16 from which 18 depends recites "SEQ ID NO:4".

11. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "MAP". It is suggested that the abbreviation be defined in the claim.

It is unclear what is meant by the polypeptide being "under the form of".

12. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the polypeptide of claim 16 "comprises an additional T-epitope". It is unclear what is the identity of the "additional T-epitope" because the polypeptide of claim 16 consists of polypeptides expressed by a recombinant host. Therefore, where does the "additional T-epitope" originate from?

13. Claims 16, 23, 24, 26, 27, 28, 29, 31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is drawn to "a purified polypeptide expressed by a recombinant cell host according to claim 9". Claim 9 is "A recombinant cell host containing a purified nucleotide according to Claim 1". Because of the open language of claim 9, i.e., host "containing" specific nucleotides, there is no requirement in claim 16 that the purified polypeptide expressed be that expressed by any of the specific SEQ ID Nos listed. Therefore, the expressed polypeptide may also be from any nucleotide sequence of the host cell itself, which is not identified or delineated. Because of this, the claimed identity and function of the claimed polypeptide is unknown.

14. Claims 23, 24, 26-29, 31, and 33 are rejected under 35 U.S.C. 112, second paragraph, because the claims recite the limitation "or an oligomeric polypeptide according to claim 16".

There is insufficient antecedent basis for this limitation in the claims as claim 16 does not recite "oligomeric polypeptide".

15. Claims 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for purified polypeptides from *M. tuberculosis*, does not reasonably provide enablement for vaccines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to "vaccine compositions" comprising a purified polypeptide from *M. tuberculosis*.

The specification is silent concerning any examples of "vaccines" which by definition protect subjects from infection with *M. tuberculosis*.

16. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a) steps by which antigen/antibody complexes are detected, b) steps which distinguish between antigen/antibody complexes and microorganism/antibody complexes, and c) steps which show how detection of antigen/antibody complexes correlate with the claimed method, i.e., detection of whole *M. tuberculosis* bacterium.

17. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to detection of whole *M. tuberculosis* bacterium in serum by mixing a purified polypeptide with the serum.

It is unclear how detection of complexes of the added polypeptide and any reactive antibodies detects the presence of whole *M. tuberculosis* bacterium.

18. Claims 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DTH response against CFP-10, does not reasonably provide enablement for diagnostic methods or kits utilizing other proteins or for antibody assays. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to detection of whole *M. tuberculosis* bacterium in serum by mixing a purified polypeptide with the serum and a kit comprising a purified polypeptide and reagents for detection of antibody/antigen complexes.

The specification only teaches Example 6, DTH responses in mice, guinea pigs, cattle, and humans using CFP10. The specification is silent concerning immunoassays using antibody and any other proteins.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

Rodney P Swartz

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

July 11, 2001